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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,469	01/25/2001	Tony Kouzarides	620-128	8432

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/01/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,469

Applicant(s)

KOUZARIDES, TONY

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 12-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 2-4 and 9-11 in Paper No. 11 (filed August 23, 2002) and peptide as the agent in Paper No. 12 (filed August 28, 2002) is acknowledged. The traversal is on the ground(s) that no lack of unity is found in the PCT application, the explanation regarding no single general inventive concept in the application by the Examiner is not sufficient, and the contribution of the claimed invention is defined by a special technical feature, which is the interaction between the CBP and Importin α . This is not found persuasive because Groups I, II and III, IV, V and VI, VII, as well as VIII and IX do not have the same special technical feature, e.g., the special technical feature of Group I is an assay method for identifying an agent which affects Importin α acetylation, and a peptide fragment of Importin α or CBP, or a nucleic acid encoding the peptide; the particular technical feature of Groups II and III is an assay method for identifying an agent which affects Importin α activity; the particular technical feature of Group IV is an assay method for identifying an agent which affects Importin α acetylation and further for providing the agent to cells to modulate the ability of Importin α to bind Importin β , to translocate into the nucleus, or to import a cargo protein; the particular technical feature of Groups V and VI is an assay method for identifying an agent which affects Importin α activity and further for providing the agent to cells to modulate the ability of Importin α to bind Importin β , to translocate into the nucleus, or to import a cargo protein; the particular technical feature of Group VII is an assay method for identifying an agent which affects Importin α acetylation and further for using the agent for manufacturing of a

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medicament for treating a disorder of Importin α activity; the particular technical feature of Group VIII and IX is an assay method for identifying an agent which affects Importin α activity and further for using the agent for manufacturing of a medicament for treating a disorder of Importin α activity; and not all claims (e.g., claims 1 and dependent claims) reflect the interaction between CBP and Importin α . Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper. Upon reconsideration, Group III will be rejoined with Group II, thus, claims 2-11 and peptide as the agent are examined.

The requirement is deemed proper and is therefore made FINAL.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification contains amino acid sequences at page 3, lines 9-10, however, the sequence identifier "SEQ ID NO:" is not recited. Please identify each sequence with a "SEQ ID NO:". Appropriate correction is required.

Claim Objections

3. Claims 2-11 are objected to because the claim cites a screening method, however, a method for "identifying" an agent is not indicated. Use of the term "An assay method for identifying an agent" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, for example, is indefinite because the claims lack essential steps in the method for identifying an agent, which affects Importin α activity. The omitted steps are: determining Importin α activity in the absence of the test compound, and the comparison of the Importin α activity in the presence and absence of the test compound. See also claims 4, 5 and 9. Claim 2 is also indefinite because of the term "Importin α activity" or "CBP", it is unclear which Importin α activity is intended, and what "CBP" means. A full spelled out word should be indicated at the first occurrence. Claims 3, 6-8 and 10-11 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

5. Claims 3, 5 and 8 are indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

6. Claim 4 is indefinite because of the use of the term "determining interaction between the first and second substances". The term "determining interaction between the first and second substances" renders the claim indefinite, it is unclear how the interaction between the first and second substances is determined.

7. Claim 5 is indefinite because the claim cites an agent which affects the ability of Importin α to bind Importin β , to translocate into the nucleus, or to import a cargo protein, however, the

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claim does not indicate how the effect of the agent on the ability of Importin α to bind Importin β , to translocate into the nucleus, or to import a cargo protein is determined.

8. Claim 9 is indefinite because of the use of the term "a region Importin α ", "a said region" or "determining interaction between said substance and the test compound". The term "a region Importin α ", "a said region" or "determining interaction between said substance and the test compound" renders the claim indefinite, it is unclear what the term "a region Importin α " means, which region is as to "a said region", e.g., is it the region of CBP, or the region of Importin α , and how the interaction between said substance and the test compound is determined.

9. Claims 10 and 11 are indefinite because the claim contains non-elected invention. Claim 10 is also indefinite because of the use of the term "at least one additional component". The term "at least one additional component" renders the claim indefinite, it is unclear what the additional component is, and what use the additional component has.

Conclusion

10. No claims are allowed.

Art of Record

There is no prior art indicating CBP acetylates Importin α at residues such as Lys 22, which would affect the activity of Importin α such as the binding Importin α to Importin β and nuclear localization of Importin α .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

October 30, 2002

Karen Cochrane Carlson Ph.D.
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER